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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/426,931	10/22/1999	WOLFGANG-REINHOLD KNAPPE	BMID9826US	2537

7590

08/29/2003

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EXAMINER
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CROSS, LATOYA I

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 08/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/426,931

Applicant(s)

KNAPPE, WOLFGANG-REINHOL

Examiner

LaToya I. Cross

Art Unit

1743

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 29 and 35-55 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 29, 35-43, 46-48 and 50-55 is/are rejected.
- 7) ☒ Claim(s) 44, 45 and 49 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

This Office Action is in response to Applicant's remarks filed on June 12, 2003 and entered as Paper No. 18. Claims 29 and 35-55 are pending.

#### *Claim Rejections - 35 USC § 103*

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 29 and 35-43, 46-48 and 50-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Good et al in view of Dreyfus.

Good et al '224 teach a diagnostic test strip for determining the presence of a specified analyte in a fluid sample. The test strip has a test membrane sandwiched between two layers. The test membrane has a sample-receiving zone containing a buffer and a fatty acid sarcosinate. The sample-receiving zone (21) is a pad made of non-woven fibrous material. The sample is absorbed by the pad, solubilizes the buffer and fatty acid sarcosinate and migrates to an adjacent reagent zone (22) containing reagent chemicals in fibrous matrix. The sarcosinate is present in a concentration of about 1.0 % by weight. Good et al '224 also disclose that the sample-receiving zone is made by imbibing a solution containing a suitable buffer and fatty acid sarcosinate into a sheet to provide the appropriate concentration. See col. 4, lines 8-16 and col. 5, lines 8-27. With respect to the test fields recited in claims 41-43 and 46-48, Good et al '224 teach test layers comprising a test zone, control zone, reagent zone and sample receiving zone. The sample receiving zone is a fibrous pad containing the fatty acid sarcosinate wetting material. The sample receiving zone overlays the other zones (reagent, test and control), as recited in claim 41. Figure 3 shows the fields overlaying one another, as recited in claim 46.

Art Unit: 1743

With respect to claim 47, Good teaches an inert plastic layer (31) having an aperture to allow sample application.

Although Good et al '224 teach fatty acid sarcosinates as wetting agents, Good et al '224 fail to specifically teach the use of oleoyl sarcosinate as the wetting agent.

Dreyfus '987 teaches fatty acid sarcosine as good wetting agents. At col. 2, lines 20-30, Dreyfus teaches higher fatty acid radicals, such as those containing more than 8 carbon atoms are suitable. Dreyfus specifically teaches the oleic acid radical as an example where valuable results may be obtained. The fatty acid sarcosines are particularly used in wet treating textile materials such as fabric-like material.

It would have been obvious to one of ordinary skill in the art to use the oleoyl sarcosine wetting agents taught by Dreyfus in the test strips of Good to provide better wetting properties to the fibrous pads and allow sample to be up taken more efficiently.

With respect to the claims requiring specific weights and thickness of the fibrous material, such would be dependent on the type of sample and amount of sample needed to conduct the analytical test. The skilled artisan would have been able to determine a suitable weight and thickness for the particular sample being collected.

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be obvious within the meaning of 35 USC 103 in view of the teachings of Good et al '224 and Dreyfus '987.

### ***Response to Arguments***

3. The declaration under 37 CFR 1.132 filed June 12, 2003 is insufficient to overcome the rejection of claims based upon Good et al in view of Dreyfus et al as set forth in the last Office

Art Unit: 1743

action because: The declaration is not commensurate in scope with the claimed invention. Specifically, the declaration provides a showing the results of using a 0.125% aqueous solution of sarcosine derivatives on sheets of Viledon-Fleece. The 0.125% aqueous solution of sarcosine is the only concentration of sarcosine used to perform the tests. Viledon-Fleece sheets are the only spreading materials used to perform the tests. The claims are not limited to the tested concentration of sarcosine (i.e. 0.125 aqueous solution). Neither are the claims limited to Viledon-Fleece sheets. In fact, several claims are directed to ranges of concentrations of the sarcosine. Also, several claims are directed to a range of porous materials to be used as the spreading material. Applicants' showing is extremely limited and therefore, cannot constitute a showing for the claimed invention, which is so broadly written. Therefore, without a further showing of data more commensurate in scope with the broad claims, the rejection over Good et al in view of Dreyfus et al is maintained.

***Allowable Subject Matter***

4. Claims 44, 45 and 49 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art of record fails to teach two overlay elements, as recited in claim 44, wherein the overlay elements face one another and whose parts are displaceable from the test strip. Further, with respect to claim 49, the prior art of record fails to teach a spreading material overlay larger than a test field and support on two sides of the test field by way of a spacer.

Art Unit: 1743

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 703-305-7360. The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 703-308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

LIC

August 25, 2003

  
Jill Warden  
Supervisory Patent Examiner  
Technology Center 1700